

Why does the FDA approve such medications and allow them to stay on the market? "There are very strong economic and political pressures when a company has spent hundreds of millions of dollars to develop a drug," Avorn says.

Wyeth-Ayerst Laboratories yanked Duract, a painkiller in the same class of drugs as ibuprofen, naproxen and others, from the market in June 1998 after reports of four deaths and eight transplants resulting from severe liver failure. According to the company, all but one of the cases occurred among patients who took the drug for more than 10 days, against the label's advice.

Just two weeks before Duract came off the market, Roche Laboratories pulled Posicor, which is used to treat high blood pressure and chest pain.

Taking Posicor with any of a number of commonly used drugs, including some heart disease treatments, could lead to potentially fatal heartbeat irregularities, the same problem that led to Propulsid's impending withdrawal.

As with Propulsid, changes to Posicor's label were designed to minimize the drug interaction risk.

"In principle, drug interactions can be addressed by appropriate labeling; however, with respect to Posicor, Roche Laboratories believes that the complexity of such prescribing information would make it too difficult to implement," the company wrote in a "Dear Doctor" letter announcing Posicor's withdrawal.

At least one drug, sorivudine for shingles, never made it to the U.S. market because of concerns about the effectiveness of label warnings. The pill was withdrawn in Japan after 15 users died in just its first month on the market. They had developed aplastic anemia, a blood disorder, after taking sorivudine with a common anti-cancer drug.

Three years later, Bristol Myers Squibb representatives argued before an FDA advisory committee that a "black box warning"—like the ones on cigarette packages—would adequately minimize sorivudine's risks.

"No one was convinced that it would work," says Raymond Woosley, chairman of pharmacology at Georgetown University in Washington, D.C., and a member of that committee, which recommended not approving sorivudine.

Because a drug already on the market, acyclovir, provided a similar benefit with far less risk, the agency followed the advisory committee's recommendation, the FDA's Behrman says. "We believed zero deaths was the only acceptable number."

RISK VS. BENEFITS

Rezulin, on the other hand, was the first drug of its class. FDA officials have said the agency sought to remove that drug from the market only after similar, safer medications became available.

"I've heard that line, but I don't buy it," Avorn says. "It's as if we don't have other medications to treat diabetes."

The risk/benefit issue arose at the FDA advisory committee meeting, where panelists recommended approval of Uprima, which would be the second impotence pill on the market.

Pre-market studies showed that the drug can trigger fainting, especially when taken with alcohol, so committee members suggested a black box warning against drinking on Uprima's label.

But panel member Thomas Graboys, who had to leave the meeting early, says he would have voted against Uprima, partly because of concerns about the label's ability to protect patients.

When the condition a drug treats isn't life-threatening, only the lowest level of risk is

acceptable says Graboys, director of the Lown Cardiovascular Center at Brigham and Women's Hospital.

Much inappropriate prescribing could be eliminated if doctors actually read package inserts or looked up the drugs in their PDRs before prescribing them, Woosley says.

Instead, they rely on memory, a Herculean task when one considers that one doctor might prescribe scores of drugs. But that's what they're taught to do in medical school, Woosley says. Doctors wrote nearly 3 billion prescriptions last year; the number is expected to reach 4 billion annually by 2004.

"We've got to start by changing the way we teach people," he says. Among his students, "the kid who gets the 'A' is the one who says 'I don't know, but I'll look that up and get back to you.'"

DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 2001

SPEECH OF

HON. CHRIS CANNON

OF UTAH

IN THE HOUSE OF REPRESENTATIVES

Wednesday, June 14, 2000

The House in Committee of the Whole House on the State of the Union had under consideration the bill (H.R. 4578) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 2001, and for other purposes:

Mr. CANNON. Mr. Chairman, I rise in support of Mr. SUNUNU's Amendment increasing funding for the Payment in Lieu of Taxes program for the FY2001 Interior Appropriations Bill. The government has an unpaid obligation to the towns and counties containing lands owned by the federal government, since these are areas that counties do not own and cannot tax. Without PILT, local governments would be forced to eliminate essential public services that benefit residents and visitors in their respective counties.

The federal government owns large portions of lands in many of the counties that I represent in Utah. For example, 93% of Garfield County is owned by the federal government. Our state uses a vast majority of the PILT reimbursements to support education. For FY2001, Utah plans to spend 49.5% of the state budget on K-12 education, among the highest in the nation. But even with this huge commitment, Utah ranks dead last in per student spending with an average of \$4,008 per year compared to the national average of \$6,407. With this much of the state owned by the federal government, Utah relies heavily on this PILT funding.

I understand that it is difficult to reconcile the many needs in the Interior budget with the limited funds available, but the PILT program has not been sufficiently funded in the past. I urge you to consider the federal responsibility and the needs of Utah's students as you cast your vote on this amendment.

HONORING SACRED HEART ROMAN CATHOLIC CHURCH OF PHOENIXVILLE, PA

HON. CURT WELDON

OF PENNSYLVANIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 15, 2000

Mr. WELDON of Pennsylvania. Mr. Speaker, it is with great pleasure and enthusiasm that I rise to congratulate Sacred Heart Roman Catholic Church in Phoenixville, Pennsylvania on the momentous occasion of its Centennial Jubilee. This year, Rev. Msgr. John Galyo and the parishioners of the Church celebrate the 100th anniversary of their parish.

Founded by Slovak immigrants in 1900 as a place to worship in their native tongue, Sacred Heart Church quickly developed into a cohesive faith community. However, the growth of the parish, both spiritually and physically, did not come without hard work, determination, and the pride of its people.

The original wooden church was destroyed by fire in the 1920s. Through the tremendous sacrifices of its selfless parishioners, a new brick building was constructed and opened for services by 1929. It remains a house of worship to this day, giving testimony to the undying spirit of the Sacred Heart community.

Although Slovak is no longer the main language spoken by the parishioners, their pride in the Slovak heritage lives on. In fact, Sacred Heart is one of only a few remaining Slovak parishes in the Archdiocese of Philadelphia. Over the course of the century, Sacred Heart has been both a blessing and an inspiration to Southeast Pennsylvania. It emerged from humble beginnings and has clearly prevailed through the often turbulent tests of time to become a thriving and enduring spiritual family.

Mr. Speaker, I ask you and my other distinguished colleagues to join me in congratulating Msgr. Galyo and the parishioners of Sacred Heart Church as they celebrate a century of tremendous achievements. May they enjoy bountiful blessings and good fortune for many more years to come.

IN HONOR OF DIANA MARIE
FALAT

HON. DENNIS J. KUCINICH

OF OHIO

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 15, 2000

Mr. KUCINICH. Mr. Speaker, today I honor Diana Marie Falat upon her reception of the Gold Key Award at the National Scholastic Art Exhibition in Washington, DC.

Diana's ceramic pieces have won several awards in the Cleveland area, including three Gold Keys, a Silver Key, and an Honorable Mention, as well as various monetary awards. For her piece entitled "Petunia", Diana was named in the Top 25 at the Ohio Governor's art show. This weekend, Diana will be honored at the Kennedy Center for the Performing Arts National Scholastic Art Exhibition with a Gold Key award—the highest award ever achieved in art by a Berea School District student.